

REMARKS

In the December 12, 2007, final Office Action, the United States Patent and Trademark Office ("the Office") rejected Claims 1, 6, 16, 21, and 31 under 35 U.S.C. § 112, first paragraph because it was said that the subject matter of these claims failed to comply with the written description requirement. The Office further rejected Claims 1, 6, 16, 21, and 31 under 35 U.S.C. § 112, second paragraph because it was said that the claims are indefinite. Claims 1, 2, 4, 5, 16-20, and 51 were rejected under 35 U.S.C. § 103(a) as being unpatentable in view of the teachings of a reference "MedManage Leads Shift in Drug Sampling Practices Online Vouchers; Pharmaceutical Marketers Turn to eMedSample to Monitor Free Sample Distribution" (September 17, 2001) (hereinafter "Reference 16:08"), another reference "RxCentric and MedManage Systems Partner to Expand Physician Use of Innovative Online Drug Sampling-Alliance Gives Pharmaceutical Companies Broader Physician Access to Drug Detailing and Sampling Programs" ("Reference 610") and an additional reference "Samples of The Future" ("Reference 9:025"), and further in view of the teachings of U.S. Patent Application Publication No. 2003/0120550 ("Peyrelevade et al."). Claims 6-10, 21-25, 31, 33-43, and 53-55 were rejected under 35 U.S.C. § 103(a) as being unpatentable in view of the teachings of a reference "iPhysicianNet and MedManage Systems Partner to Offer a New Electronic And Voucher Sampling Service to Thousands of U.S. Physicians" (hereinafter "Reference 20:16"); and four already cited references: (i) "For Consumers Free Samples Are a Virtual Reality: Pharmaceutical Samples Were Once Strictly Passed From Manufacturing to Physician to Patient, But Online Marketing Tactics Are Rearranging That Order" ("Reference 9:026"); (ii) "Samples of the Future" ("Reference 9:025"); (iii) "RxCentric and MedManage Systems Partner to Expand Physician Use of Innovative Online Drug Sampling-Alliance Gives Pharmaceutical Companies Broader Physician Access to Drug Detailing and Sampling Programs" ("Reference 610"); (iv)

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"MedManage Tracks Troublesome Pill Samples" ("Reference 635"); and (v) "MedManage Leads Shift in Drug Sampling Practices Online Vouchers; Pharmaceutical Marketers Turn to eMedSample to Monitor Free Sample Distribution" ("Reference 16:08"); in view of the teachings of a new patent reference, U.S. Patent Application Publication No. 2003/0120550, to Peyrelevade et al. Claim 52 was rejected under 35 U.S.C. § 103(a) in view of the teachings of "MedManage Leads Shift in Drug Sampling Practices Online Vouchers; Pharmaceutical Marketers Turn to eMedSample to Monitor Free Sample Distribution" ("Reference 16:08"); in view of the teachings of a new patent reference, Peyrelevade et al. Claim 44 was rejected under 35 U.S.C. § 103(a) as being unpatentable in view of the teachings of "RxCentric and MedManage Systems Partner to Expand Physician Use of Innovative Online Drug Sampling-Alliance Gives Pharmaceutical Companies Broader Physician Access to Drug Detailing and Sampling Programs" ("Reference 610"), and further in view of the teachings of Peyrelevade et al. Rejections Under 35 U.S.C. § 112, first paragraph

Applicants' specification describes as follows, at page 7, lines 6-18:

After the brand manager 204 has selected a group of prescribers 210, the brand manager 204 produces a set of brand rules 206 which define the availability of drug samples to each of the prescribers 210. The set of brand rules 206 may cause one prescriber's drug sample availability and characteristics to be different from those of another prescriber. Thus, for each prescriber there is a virtual drug sample cabinet tailored specifically for that prescriber. Preferably, the group of prescribers 210 is divided into segments. The brand rules provide personalization and customization for each segment. Many other personalization capabilities to tailor the distribution of drug samples to prescribers 210 are possible, such as various delivery methods; various drug strengths; trademark and local presentation of drug samples; customized drug disclaimers; specific product, package, and brand Web sites; and facilitating the scheduling of prescriber interactions with sales representatives or medical science liaisons.

Thus, brand Web sites, as a segment, can facilitate personalization and customization depending on the brand rules, and brand rules include that "which define the availability of drug samples to each of the prescribers," as recited above. This description of applicants' specification among other disclosure supports "set of brand rules for guiding a distribution of drug samples of a drug to cause a prescriber's drug sample availability and characteristics while a member of one brand Web site to be different from the same prescriber while a member of another brand Web site," as recited in Claim 1.

Yet, the Office requires much more from the applicants by asking that "[t]he Applicant needs to point to the Examiner where in the Applicant's specification said limitations are recited." In other words, the Office wants a verbatim recitation from the specification to support limitations in the claims. This is improper and there is no legal support for such a requirement by the Office. Even the M.P.E.P. § 2163 explains as follows:

Capon v. Eshhar, 418 F.3d 1349, 1357, 76 USPQ2d 1078, 1085 (Fed. Cir. 2005)("The 'written description' requirement must be applied in the context of the particular invention and the state of the knowledge As each field evolves, the balance also evolves between what is known and what is added by each inventive contribution."). If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met. See, e.g., Vas-Cath, 935 F.2d at 1563, 19 USPQ2d at 1116; Martin v. Johnson, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972) (stating "the description need not be in *ipsis verbis* [i.e., "in the same words"] to be sufficient").

Because the Office requires the same words to appear in the specification to support claim limitations, the Office has failed to state a proper 35 U.S.C. § 112 rejection. Withdrawal of the rejections under 35 U.S.C. § 112, first paragraph, is respectfully requested.

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Rejections Under 35 U.S.C. § 112, second paragraph

The Office indicated that the underlined portions of the claim limitation "a computer-readable set of brand rules for guiding a distribution of drug samples of a drug to cause a prescriber's drug sample availability and characteristics while a member of one brand Web site to be different from the same prescriber while a member of another brand Web site." as recited by Claim 1 among other claims, is indefinite. To understand what is meant by indefinite, M.P.E.P. § 2173.02 explains as follows:

See . . . Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354, 1366, 71 USPQ2d 1081, 1089 (Fed. Cir. 2004) ("The requirement to 'distinctly' claim means that the claim must have a meaning discernible to one of ordinary skill in the art when construed according to correct principles Only when a claim remains insolubly ambiguous without a discernible meaning after all reasonable attempts at construction must a court declare it indefinite.").

Accordingly, a claim term that is not used or defined in the specification is not indefinite if the meaning of the claim term is discernible. *Bancorp Services, L.L.C. v. Hartford Life Ins. Co.*, 359 F.3d 1367, 1372, 69 USPQ2d 1996, 1999-2000 (Fed. Cir. 2004) (holding that the disputed claim term "surrender value protected investment credits" which was not defined or used in the specification was discernible and hence not indefinite because "the components of the term have well recognized meanings, which allow the reader to infer the meaning of the entire phrase with reasonable confidence").

The claim limitation at issue is "a computer-readable set of brand rules for guiding a distribution of drug samples of a drug to cause a prescriber's drug sample availability and characteristics while a member of one brand Web site to be different from the same prescriber while a member of another brand Web site." as recited by Claim 1. By rejecting this claim limitation as indefinite, the Office is indicating that the claim is "insolubly ambiguous without a discernible meaning." This surely is incorrect. The claim limitation plainly explains that there is a prescriber. There is also drug sample availability and characteristics. That drug sample

availability and characteristics can be associated with the prescriber while that prescriber is a member of one brand Web site. Furthermore, that drug sample availability and characteristics are different if the same prescriber is a member of another brand Web site. It is unclear to applicants why the Office would say that there is no discernible meaning in the recited claim limitation. Unless of course, it is for the purpose of shoehorning the claim limitation in a way that facilitates the use of Peyrelevalde et al.: "For purpose of art rejection, said limitation would be interpreted as customizing a website displayed to a customer based upon the brand of said website and based upon said customer's profile and also outsourcing the payment for products in said website."

That is improper. See In re Steele, 305 F.2d 859,134 USPQ 292 (CCPA 1962) (it is improper to rely on speculative assumptions regarding the meaning of a claim and then base a rejection under 35 U.S.C. § 103 on these assumptions). Given the assumption of the Office, clearly there are some discernible meanings. But since 1962, an indefinite rejection under 35 U.S.C. § 112, second paragraph, has been unavailable to the Office for the purpose of shoehorning the claim limitation so that it somehow fits within a reference, such as Peyrelevalde et al. The subject matter of the claimed invention has to do with drug samples, which are available for free to prescribers.

Thus, there is no need for "outsourcing the payment for products in said website" as required by Peyrelevalde et al. Peyrelevalde et al. is directed to a software module for use in constructing different Web sites so that each Web site may incorporate common information while also incorporating information unique to the Web site to sell the same product, such as lipsticks. Peyrelevalde et al. allows a brand owner to construct a single software module that may be used in the Web sites of multiple resellers. As applicants have indicated previously, drug samples are available for free to prescribers. Additionally, it is a bizarre interpretation that

lipsticks or other beauty products can be construed as drug samples. No one skilled in the art of pharmacology would mistake drug samples as lipsticks or other beauty products. This is the sort of speculative assumption that is inappropriate. Withdrawal of the rejections under 35 U.S.C. § 112, second paragraph, is respectfully requested.

Rejections Under 35 U.S.C. § 103(a)

Applicants are unable to find, and the Office has failed to show, where the cited and applied references teach or suggest "a computer-readable set of brand rules for guiding a distribution of drug samples of a drug to cause a prescriber's drug sample availability and characteristics while a member of one brand Web site to be different from the same prescriber while a member of another brand Web site," as recited by Claim 1. Peyrelevade et al. indicates in his Field of the Invention as follows: "The invention relates to systems and methods for facilitating electronic commerce using the Internet. It may have particular benefit for enabling the same product to be sold through multiple portals using a modular construction."

For emphasis, the same product is sold through multiple portals. In contrast, the claimed invention requires "a prescriber's drug sample availability and characteristics while a member of one brand Web site to be different from the same prescriber while a member of another brand Web site," as recited in Claim 1. Requiring the same product to be sold through multiple portals under any interpretation cannot disclose "a prescriber's drug sample availability and characteristics while a member of one brand Web site to be different from the same prescriber while a member of another brand Web site," as recited in Claim 1.

In addition, Peyrelevade et al. explains that these products are beauty products, such as lipstick, lipliner, an eyeliner, an eye shadow, a blush, a concealer, a base, a mascara, an anti-wrinkle product, an anti-aging product, a tanning product, a cleansing product, a hair product, and a beauty care product. See Col. 14, Claim 11. One with ordinary skill in the art of

pharmacology would not mistake drug samples for lipsticks and other beauty products. Drug samples must be prescribed by a prescriber and they are available for free to the prescriber who would prescribe drug samples to patients. A consumer does not need a doctor to prescribe lipsticks.

Given the defects of Peyrelevade et al., there is no need for its combination with other cited and applied references because these other references cannot cure the defects of Peyrelevade et al. Thus, the Office has failed to state a *prima facie* case of obviousness. And because the Office has failed the *prima facie* case of obviousness, the rejections should be withdrawn. Independent Claims 1, 6, 16, 21, and 31 are clearly patentably distinguishable over the cited and applied references. Claims 2, 4, 5, 7-10, 17-20, 22-25, 33-45, and 51-55 are allowable because they depend from allowable independent claims and because of the additional limitations added by those claims. Consequently, reconsideration and allowance of Claims 1, 2, 4-10, 16-25, 31, 33-45, and 51-55 is respectfully requested.

Respectfully submitted,

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